



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,870	02/14/2002	Mark E. Salvati	LD0210 (NP)	9453

23914 7590 07/01/2004

STEPHEN B. DAVIS
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON, NJ 08543-4000

EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,870	SALVATI ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 4-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' amendments submitted April 7, 2004 necessitate the following restriction requirements.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 4-13, drawn to method of treating cancers expressing the estrogen receptor or cancers containing the progesterone receptor (including prostate cancer, breast cancer, endometrial cancer) by administering the compound, wherein the compounds are those defined in claims 8 or 12, classified in class 424, subclass 410, 425.
 - II. Claims 4-7, 10-11, drawn to method of treating cancers expressing the estrogen receptor or cancers containing the progesterone receptor (including prostate cancer, breast cancer, endometrial cancer) by administering the compounds, wherein Z1 and Z2 are oxygen, and the compounds are other than those define in claims 8 or 12 classified in class 424, subclass 410, 425.
 - III. Claims 5-7, 10-11 drawn to method of treating cancers expressing the estrogen receptor or cancers containing the progesterone receptor (including prostate cancer, breast cancer, endometrial cancer) by administering the compound, wherein Z1 and Z1 are not oxygen classified in class 424, subclass 410, 425, 246.
 - IV. Claims 4-13, drawn to method of treating cancers other than those encompassed in group I by administering the compound, wherein the compounds are those defined in claims 8 or 12, classified in class 424, subclass 410, 425.

- V Claims 4-7, 10-11, drawn to method of treating cancers other than those encompassed in group II by administering the compounds, wherein Z1 and Z2 are oxygen, and the compounds are other than those define in claims 8 or 12 classified in class 424, subclass 410, 425.
- VI Claims 5-7, 10-11 drawn to method of treating cancers other than those defined in group III by administering the compound, wherein Z1 and Z1 are not oxygen classified in class 424, subclass 410, 425, 246.
- VII Claims 4-13, drawn to method of treating conditions or disorders which are not cancer by administering the compounds, wherein Z1 and Z2 are oxygen, and the compounds are other than those define in claims 8 or 12 classified in class 424, subclass 410, 425.
- VIII Claims 5-7, 10-11 drawn to method of treating conditions or disorders, which are not cancer by administering the compound, wherein Z1 and Z2 are oxygen, and the compounds are other than those define in claims 8 or 12 classified in class 424, subclass 410, 425.
- IX Claims 5-7, 10-11 drawn to method of treating conditions or disorders, which are not cancers by administering the compound, wherein Z1 and Z1 are not oxygen classified in class 424, subclass 410, 425, 246.
2. Inventions groups I-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions they have different functions or model of operation. Particularly, the several inventions above are independent and distinct, each from the other, as they are directed to treating diseases with distinct etiologies and symptoms, and/or employ structurally distinct compounds, and have acquired a separate status in the art of treating as a separate subject matter with distinct compounds for inventive effect and require independent searches. They therefore have different issues regarding patentability and enablement. It is noted that a reference to one treatment would not be a reference to another treatment under 35 U.S.C. 103. Further, the claims read on a multitude of compounds, and a variety of disorders, which would require many field of searches that would be an undue burden on the Examiner. Therefore, restriction for examination purposes is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

S.  **SHENGJUN WANG**
Shengjun Wang **PRIMARY EXAMINER**

May 26, 2004